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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/081,050 | 02/20/2002 | David W. Osborne | 359872001400 | 2420 |

7590 10/01/2004

A James Nelson Esq
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1615

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment

Application No.

10/081,050

Examiner

Lakshmi S Channavajjala

Applicant(s)

OSBORNE, DAVID W.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 16 March 2004.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☒ The reason(s) below:

a copy of the final office action dated 3-16-04 is attached to this paper.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



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7590 03/16/2004
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,050

Applicant(s)

OSBORNE, DAVID W.

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 4, 7-22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of amendment and response dated 12-8-03 is acknowledged.

Claims 2, 3, 5, 6, 23, 24 and 26 have been canceled.

Instant claims are amended to recite a method of reducing the number of non-inflammatory acne or a method of treating non-inflammatory acne comprising a step of topically applying a dermatological composition comprising dapsone to the non-inflammatory acne lesions.

The rejection of record (dated 7-11-03) has been maintained for the following reasons:

Claim Rejections - 35 USC § 102

Claims 1-7, 13, 14, 20, 21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 or US 5,863,560, both patented to Osborne ('085 and '560).

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references teach dapsone in a topical composition and for the same purpose i.e., treatment of acne.

Accordingly, the ability to treat inflammatory and non-inflammatory acne is inherent to the composition of both the references. Osborne also discloses the method of preparing the dapsone composition involving the claimed steps (col. 7, lines 10-25 of both patents). With respect to the

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method of preventing non-inflammatory acne lesion from becoming inflammatory acne, the dissolved portion of dapsone in the composition of Osborne passes through stratum corneum in to lower third of pilosebaceous unit, whereas the microparticulate dapsone crosses stratum corneum only minimally. Thus, once the herpes lesion vesicle ruptures and the stratum corneum is no longer in place, then the microparticulate dapsone is only dissolved and is released for sustained and significant therapeutic benefit, thus preventing the development of inflammatory lesion (col. 2). Therefore, Osborne ('085 and '560) anticipates the instant claimed invention.

Claim Rejections - 35 USC § 103

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,964 to Singleton et al ('964) in view of Osborne ('085 or '560).

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. However, '964 fail to explicitly teach dapsone for treating acne.

The teachings of Osborne ('085 and '560) have been discussed above. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to use dapsone in the composition of '964 as an additional anti-acne agent because Osborne teaches dapsone as an effective anti-acne agent and using dapsone in an dissolved and a microparticulate forms in the same composition enables immediate treatment of inflammation as well as prevention of

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inflammatory lesions. Further, preparing the dapson containing composition in the different formulations such as a cream, lotion, gel without losing the anti-acne activity would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments filed 12-8-03 have been fully considered but they are not persuasive.

In view of the amendment and cancellation of claims, the rejections of claims under 35 USC 112, first and second paragraphs have been withdrawn.

Claim Rejections - 35 USC § 102:

Applicants argue that Instant claim 1 now recites a method "for reducing the number of non-inflammatory acne lesions", which has not been taught or disclosed by both Osborne patents ('085 and '050). Applicants argue that not all acne is the same, some result in inflammation and inflammatory lesions, while other acne does not. Applicants argues that Osborne patents cited under 35 USC § 102 fail to disclose even a single instance of treating non-inflammatory acne lesions with a dermatological composition, let alone for reducing the number of non-inflammatory acne lesions. Applicants further argue that examiner failed to provide a basis in fact and, or, technical reasoning to reasonably support a conclusion that an allegedly inherent characteristic "necessarily flows" from the teachings of the cited art and an evidence for the basis. Applicants argue that instant new use of a known composition, based on unknown properties are patentable. Therefore, applicant states that the instant claims are patentable.

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However, applicants arguments are not found persuasive because the prior art references teach the same active agent dapson, formulated in the same manner as claimed i.e., comprising dissolved and microparticulate dapson. Osborne patents teach that intact stratum corneum lines the upper third of the pilosebaceous unit into which the sebaceous duct secrete sebum. Further, Osborne patents teach that dapson formulation is largely delivered in this sebum secreting duct and also cross this region (col. 1-2). Acne is a known multifactorial disease that involves increased amounts of sebum production in the sebaceous follicles resulting in hyperkeratosis of the follicular epithelium, which in turn leads to the obstruction of the duct by horny plaque and formation of a non-inflammatory comedones. It is implicit from the teachings of Osborne patents that dapson formulation delivered to that same portion of pilosebaceous unit, where the process of forming non-inflammatory comedones begins. Therefore, it is inherent that the dapson formulation of Osborne patents possesses the ability to reduce the number of non-inflammatory acne lesions formed and thus provides a treatment for non-inflammatory acne lesions. Further, on Page 5 of the instant specification, applicants also describe that the claimed composition provides greatest amount of pharmaceutical available for immediate partition out of the stratum corneum and into the epidermis. Therefore, Osborne patents anticipate instant claims.

Claim Rejections - 35 USC § 103

Applicants argue that the instant rejection fails to teach or suggest each and every claim limitation because neither of the Osborne patents expressly or inherently teach or disclose methods for treating non-inflammatory acne and that the rejections concludes by making a reference only to the treatment of inflammation and inflammatory lesions. Applicants did not

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argue the teachings of Singleton ('964). With respect to Osborne patents, examiner provided a detailed technical basis for concluding the dapsona composition of Osborne patents inherently possess the property of reducing the number of non-inflammatory acne lesions. As explained, dapsona is taught be delivered at the very upper third stratum corneum portion of the pilosebaceous unit, where the excess sebum production first results in non-inflammatory comedones, which then proceeds to form inflammatory comedones upon infection. Applicants also teach in the instant specification that the instant method of treatment and/or reducing non-inflammatory acne lesions is achieved by the same mechanism of delivery. Accordingly, it is examiner's position that the mechanism of action being same in the instant and the cited patents, the latter anticipates the instant invention. Accordingly, for the reasons set forth, instant claims are obvious over Singleton ('94) in view of Osborne patents ('085 or '560).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
March 14, 2004



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600